

Usability of medical devices

This Med-Info is directed at:

- manufacturers of medical devices
- manufacturers of components and accessories for medical devices

Background:

User-friendliness and ergonomics have become important quality characteristics for medical devices. Manufacturers and users have taken action: Users of medical devices emphasize a high degree of user-friendliness. The manufacturers of medical devices are responding to the requirements of their users through appropriate measures and improvements. By developing better man-machine interfaces, the avoidance of "user errors" receives more importance.

Now there are standards for usability which determine how usability has to be integrated in the development process. TÜV SÜD Product Service explains what the new standards are all about and illustrates the advantages to the manufacturer.

What standards are there?

IEC 60601-1-6 (Medical Electrical Equipment – Usability)

IEC 62366 (Medical Devices – Usability)

Since when have they been valid?

The IEC 60601-1-6 has been harmonized under the Medical Device Directive (93/42/EWG) since July 2006. The ISO IEC 62366 has been published as draft.

What is the goal of the standards?

- To minimize the risk of use error.
- To ensure safety through specific development of suitable man-machine interfaces.

How is the degree of usability assessed?

Mainly safety is evaluated, i.e. to what extent use errors can be minimized during the selection of a suitable user interface. Effectiveness is also measured. An evaluation of the accuracy and completeness with which a particular goal can be reached is done. An efficiency assessment determines how much effort is necessary to reach this goal, and finally there is a subjective test of the degree of user satisfaction to evaluate the acceptance or attitude of the user towards the use of the product.

What do the standards require?

The standards require a "usability engineering process" from manufacturers. That means that methods from ergonomics must be used during the development phase in order to develop an optimal man-machine interface. It also requires a written "usability specification" which specifies all measures in terms of usability of the device.

Among other things, the standards also address purpose and proper use ("equipment application specification"), by requiring descriptions of typical application scenarios.

All measures concerning the use of the device must be verified with regard to their implementation and effectiveness. The standards place a special focus on validation. Validation must be planned clearly. The procedures, operating scenarios, environmental scenarios, and test user groups must be specified to permit assessment of the effectiveness of the man-machine interface. The validation must then be carried out in accordance with the specified plan, and, if necessary, measures must be taken to improve the user interface.

How can TÜV SÜD Product Service help you?

TÜV SÜD Product Service has set up a comprehensive service offer. First of all we offer conformity assessment procedures based on your documentation:

- assessments as an extended workbench
- conformity assessments in the context of Annex III
- CB assessments

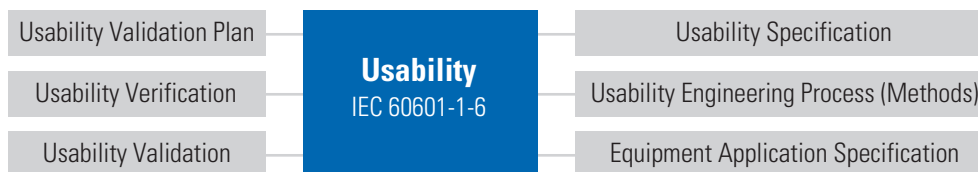
Beside the assessment of the usability file we can offer you the following services in cooperation with our partner lab:

- usability validation under realistic conditions
- assessment of the usability in parallel with your engineering process
- training in the new standards and in practical aspects of usability
- TÜV SÜD mark for usability

Why should you subject yourself to such a test?

You achieve optimal protection against use errors.

- You demonstrate that you have developed the man-machine interfaces of your product based on the state of the art in research and technology.
- You have a clear competitive edge through the greater satisfaction of users.
- The trusted and widely recognized TÜV SÜD test mark represents a marketing advantage.



Your contact at TÜV SÜD Product Service GmbH will be happy to advise you about further details.

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